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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,462	11/24/2003	Thomas J. Boyd	7052-01	4081

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EXAMINER

ROBERTS, LEZAH

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/720,462	Applicant(s) BOYD ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-15 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

This action is **NON-FINAL**.

All previous rejections have been withdrawn unless stated infra.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claims*

#### **Claim Rejections - 35 USC § 103 - Obviousness**

1) Claims 1-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551) in view of Leung et al. (US 2001/0022964).

Schmitt teaches oral care and dental compositions made with film-forming materials. The compositions comprise abrasives, tensides, polishing agents, aromatizing substances as well as additional usual additives characterized in that the active agents and additives are formulated in a binding agent or a mixture of binding agents which consist of water-soluble or water-swellaable, physiologically acceptable film forming substances and that this mixture is formulated into a film. Film forming agents include starch, gelatins, glycerols and/or sorbite as well as natural and synthetic resins and gums. Aromatizing substances include peppermint, spearmint oil and cinnamon oil (all flavoring oils) (col. 2, lines 5-33). The thickness of the films ranges from 0.1 to 3

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mm. The film can be applied onto a carrier film, the composition of which corresponds to the binding agent of the mass (film) (col. 2, lines 45-61), encompassing the instant claims insofar as an orally acceptable vehicle. The composition may also be molded into any desired shape. Through the insertion into the mouth cavity and in connection with the saliva and the intensive movement of the toothbrush the strip is pre-dissolved and dissolved so that the components can develop their full activity. After use and subsequent mouth washing with water no remains are retained in the mouth (col. 3, lines 1-16). The compositions may also be used for cleaning and care of artificial teeth and dentures. For this purpose a multiple coating is particularly advantageous, which comprises the cleaning, disinfecting and acidic compositions in one layer, while, optionally separated by an also water-soluble barrier layer, the second layer comprises the CO<sub>2</sub> or O<sub>2</sub> releasing substances. The reference differs from the instant claims insofar as it does not disclose using hydroxyalkyl cellulose in combination with starch as the film forming agents.

Leung et al. teach fast dissolving orally consumable strips. The strips are made from water-soluble polymers and are effective at killing plaque-producing germs that cause dental plaque, gingivitis and bad breath. The films also include pharmaceutically active agents. The film-forming agents used in the films are selected from the group consisting of pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, starch and mixtures thereof. They are incorporated at levels ranging from preferably 60 to 65 % weight of the film (paragraph 0033). The films also include essential oils as

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antimicrobial/flavoring agents, water, antimicrobial agents (including fluoride), additional film-forming agents, plasticizing agents, additional flavoring agents, sulfur precipitating agents, saliva stimulating agents, cooling agents, surfactants, stabilizing agents, emulsifying agents, thickening agents, binding agents, coloring agents, sweeteners, fragrances, and the like (paragraph 0034). Flavoring is incorporated into the films generally ranging from 0.1 to 30% by weight of the film (paragraph 0053). Preferred binding agents include starch, in amounts ranging from about 0 to about 10 wt % of the film (paragraph 0044). The invention provides a physiologically acceptable film, which is particularly well adapted to adhere to and rapidly dissolve in the mouth of a consumer. The film delivers at least one oral care agent, such as antimicrobial agents and salivary stimulants. The film former used to make the films entraps the oral care agents in the oral cavity to provide extended efficacy. They are also breath fresheners effective against oral malodor. The rapidly dissolvable films may also act as a vehicle for administering a pharmaceutically active agent orally, through a mucous membrane or an open wound of a patient (paragraph 0020-0022). The reference differs from the instant claims insofar as it does not teach the compositions having all the components of a dentifrice (paste or powder) such as abrasives.

It would have been obvious to one of ordinary skill in the art to have used the film-forming agents in the dentifrice compositions of the primary reference motivated by the desire to produce a dentifrice with physiologically acceptable therapeutic films, dissolves quickly, provides extended efficacy and is able to deliver active agents

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through a mucous membrane or an open wound of a patient as taught by the secondary reference.

2) Claims 1-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551) in view of Zerbe et al. (US 2003/0053962).

Schmitt teaches oral care and dental compositions made with film-forming materials. The reference differs from the instant claims insofar as it does not disclose using hydroxyalkyl cellulose in combination with starch as the film forming agents.

Zerbe et al. teach fast dissolving breath freshening films that may also be incorporated into food items. The films are made from a combination of film forming agents hydroxypropyl cellulose and modified starch. Also incorporated is a breath freshening flavor, which is the functional component. It has been discovered that a combination of hydroxypropyl cellulose and a modified starch provides improved solubility properties that enable rapid disintegration of the film upon contact with even low levels of moisture. The improved rapid disintegration properties of the flavored films of the invention are believed to be attributable to the excellent properties of the modified starch as a disintegrant. The modified starch may be chosen from cornstarch, potato starch or tapioca starch. Also, the improved water dissolution kinetics of hydroxypropyl cellulose as compared with conventional film polymers such as polyvinylpyrrolidone and hydroxypropylmethyl cellulose impart rapid disintegration properties to the films of this invention. The film may be one layer or multi-layer. A multiple layer breath freshening film is provided which includes a first layer having at least one hydroxypropyl cellulose,

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at least one modified starch, and at least one flavoring ingredient; and a second layer including at least one water-soluble polymer and a second flavoring ingredient. The reference differs from the instant claims insofar as it does not teach the compositions having all the components of a dentifrice (paste or powder) such as abrasives.

It would have been obvious to one of ordinary skill in the art to have used the polymer combination in the composition of the primary reference motivated by the desire to make functional flakes that dissolve rapidly when in the mouth under any mouth conditions and will deliver the therapeutic agent rapidly to the mouth.

3) Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmidt (US 5,354,551) in view of Zerbe et al. (US 2003/0053962) as applied to claims 1-14 above, and further in view of Sintov et al. (US 5,425,953).

The primary and secondary references are discussed above. The references differ from the instant claims insofar as they do not teach using hydrogen peroxide as a whitening agent.

Sintov et al. teach oral film compositions comprising peroxide as a bleaching agent. Carbamide peroxide or hydrogen peroxide may be used to treat gingivitis or to prevent dental plaque. Hydrogen peroxide is an antimicrobial agent and is especially useful against anaerobic bacteria. It may also be used to bleach teeth. Therefore when incorporated into a dentifrice one or more dental conditions can be treated with one treatment regime. The peroxide is incorporated into a composition comprising hydroxypropyl cellulose, a film is formed when in the oral cavity and the hydrogen

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peroxide is released. The reference differs from the instant claims insofar as it does not teach incorporating hydrogen or carbamide peroxide into a film flake.

It would have been obvious to one of ordinary skill in the art to have incorporated hydrogen peroxide into the flakes of the combined primary and secondary references motivated by the desire to have functional flakes that provide a cosmetic (cleaning the teeth) and therapeutic benefits with one agent as disclosed by the secondary reference.

### **Obvious-Type Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 and 44-46 of copending Application No. 10/739803 in view of Zerbe et al. (US 2003/0053962).



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Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive insofar as they both recite flakes or films made from water-soluble polymers having functional materials entrained therein. The instant application recites species of the copending application insofar as it teaches a particular film forming combination comprising a hydroxyalkyl cellulose whereas the copending application is broader teaching several types of film forming polymers that may be used to form the films such as polyvinylpyrrolidone, methacrylates and hydroxyalkyl cellulose. Zerbe et al. teach oral compositions comprising hydroxyalkyl cellulose and starch that quickly dissolves when placed into the oral cavity and can deliver therapeutic agents to the mouth.

It would have been obvious to one of ordinary skill in the art to have used water hydratable film forming matrix of Zerbe et al. in the film flakes of the instant and copending claims motivated by the desire to make functional flakes that dissolve rapidly when in the mouth under any mouth conditions and will deliver therapeutic agents rapidly to the mouth.

This is a provisional obviousness-type double patenting rejection.

2) Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 and 44-46 of copending Application No. 10/860377 in view of Zerbe et al. (US 2003/0053962). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite a dentifrice that contains film matrices that are

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decorative and shaped. The films comprise a colorant and flavorant, and the film matrices are made up of the same materials (water soluble hydroxyalkyl cellulose polymer and starch). They also may comprise a therapeutic agent, a cosmetic constituent, an antibacterial agent or a calcium or fluoride salt. The sets of claims differ from one another insofar as the instant claims are a species of the copending claims in certain regards such as the water-soluble polymer used. The copending claims are broader in regards of the type of water hydratable polymer that may be used to make the films. Zerbe et al. teach oral compositions comprising hydroxyalkyl cellulose and starch that quickly dissolves when placed into the oral cavity and can deliver therapeutic agents to the mouth.

It would have been obvious to one of ordinary skill in the art to have used water hydratable film forming matrix of Zerbe et al. in the film flakes of the instant and copending claims motivated by the desire to make functional film flakes that dissolve rapidly when in the mouth under any mouth conditions and will deliver therapeutic agents rapidly to the mouth.

This is a provisional obviousness-type double patenting rejection.

### **Allowable Subject Matter**

Claims 6-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims are distinct from the prior art. Claim 6 is distinct because the carrier is specified as a gel, which makes it distinct from saliva

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or water. Claim 7 is distinct from the prior art because it gives a specific amount of film flakes that may be incorporated into the dentifrice and there is no way of determining how much of the film flakes would be found in saliva when the film is placed into the mouth.

Claims 1-5 and 8-15 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts  
Patent Examiner  
Art Unit 1614

Frederick Krass  
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